

IN THE DRAWINGS

The drawings were objected to in the Office Action dated February 16, 2005. Applicant submits formal drawings herewith. The attached sheets of drawings include changes to FIG. 1. The sheet labeled “Replacement Sheet,” which includes FIG. 1, replaces the original sheet including FIG. 1.

INTERVIEW SUMMARY

Applicants appreciate the courtesy extended for the personal interview between Applicants' representative Catherine I. Klima-Silberg and Examiner Alyssa M. Alter on April 27, 2005. In the interview, the rejections made in the previous Office Action dated February 16, 2005, and the reference cited therein were discussed in light of the pending claims.

REMARKS

This responds to the Office Action dated February 16, 2005.

Claims 11, 17, 18, 26, 27 and 29 are amended, claims 16 and 30 are cancelled without prejudice, and no claims are added; as a result, claims 11-15, 17-29, and 31-32 are now pending in this application. The amendments to the claims are fully supported by the specification as originally filed, and no new matter has been added.

Applicants hereby respectfully request further examination and reconsideration of the application, in view of the following remarks.

§112 Rejection of the Claims

Claims 27- 29 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

In response, claims 27 and 29 have been revised. No new matter has been entered. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, basis of rejection of claims 27-29.

§102 Rejection of the Claims

Claims 11-12 and 16-18 stand rejected and claims 26 and 29-32 were rejected under 35 U.S.C. § 102(e) as being anticipated by Salo (U.S. Publication No. 2003/0125774). Applicants respectfully traverse these rejections.

“If the examination . . . does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of [a] patent.” *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)(emphasis added). Applicants respectfully submit that the

Office Action dated February 16, 2005 has not made out a *prima facie* case of anticipation on at least three grounds.

First, anticipation requires that the claimed subject matter be *identically* disclosed in the prior art. *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972). It is not enough that the reference disclose all the claimed elements in isolation; rather, the prior art reference must disclose each element of the claimed invention “*arranged as in the claim.*” *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983))(emphasis added). The reference relied upon must teach or suggest *all* the limitations of the claims. See *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)(stating “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art”)(emphasis added)). To overcome the defense of anticipation, “it is only necessary for the patentee to show some tangible difference between the invention and the prior art.” *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172 (9th Cir. 1981).

Second, the fact that a certain result or characteristic *may* occur or be present in the prior art is *not sufficient to establish the inherency* of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)(stating “[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient”)(emphasis in original). “To establish inherency, the extrinsic evidence must *make clear that the missing descriptive matter is necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(emphasis added).

Third, a holding of no anticipation may be found in instances where the prior art application or use is different than the applicant’s application or use. *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1183 (2001). “The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import.” MPEP § 608.01(o).

Claim 11-12 and 16-18:

Applicants have amended claim 11 to include the subject matter of claim 16. As a result, claim 11 includes “measuring a temperature change in the coronary sinus.” (Applicants’ claim 11).

Applicants cannot find in Salo “measuring a temperature change in the coronary sinus.” Rather, Salo describes “comparing a measured coronary vein blood temperature with a long-term average coronary vein temperature.” (Salo, [0018]). In the Interview Summary dated April 29, 2005, it was asserted that “comparing a measured coronary vein blood temperature with a long-term average coronary vein temperature, as described by Salo (US Patent Publication 2003/0125774) on page 2, paragraph 18, is infact [sic] measuring temperature changes in the coronary sinus.” However, Applicants respectfully submit that a coronary vein is not the same as the coronary sinus.

To help explain the difference between a coronary vein and the coronary sinus, Applicants have provided two objective sources which clearly recognize the fact that the coronary sinus is not the same as a coronary vein. First, Applicants have provided FIG. 556 (shown below) and related text from Anatomy of the Human Body, by Henry Gray, bibliographic information for which is as follows:

AUTHOR: Gray, Henry, 1825-1861

TITLE: Anatomy of the Human Body, by Henry Gray. 20th ed., thoroughly rev.
and re-edited by Warren H. Lewis.

PUBLISHED: Philadelphia: Lea & Febiger, 1918.

ISBN: 1-58734-102-6.

CITATION: Gray, Henry. Anatomy of the Human Body. Philadelphia: Lea & Febiger, 1918; Bartleby.com 2000. www.bartleby.com/107/. [May 5, 2005].

ON-LINE: Published May 2000 by Bartleby.com.

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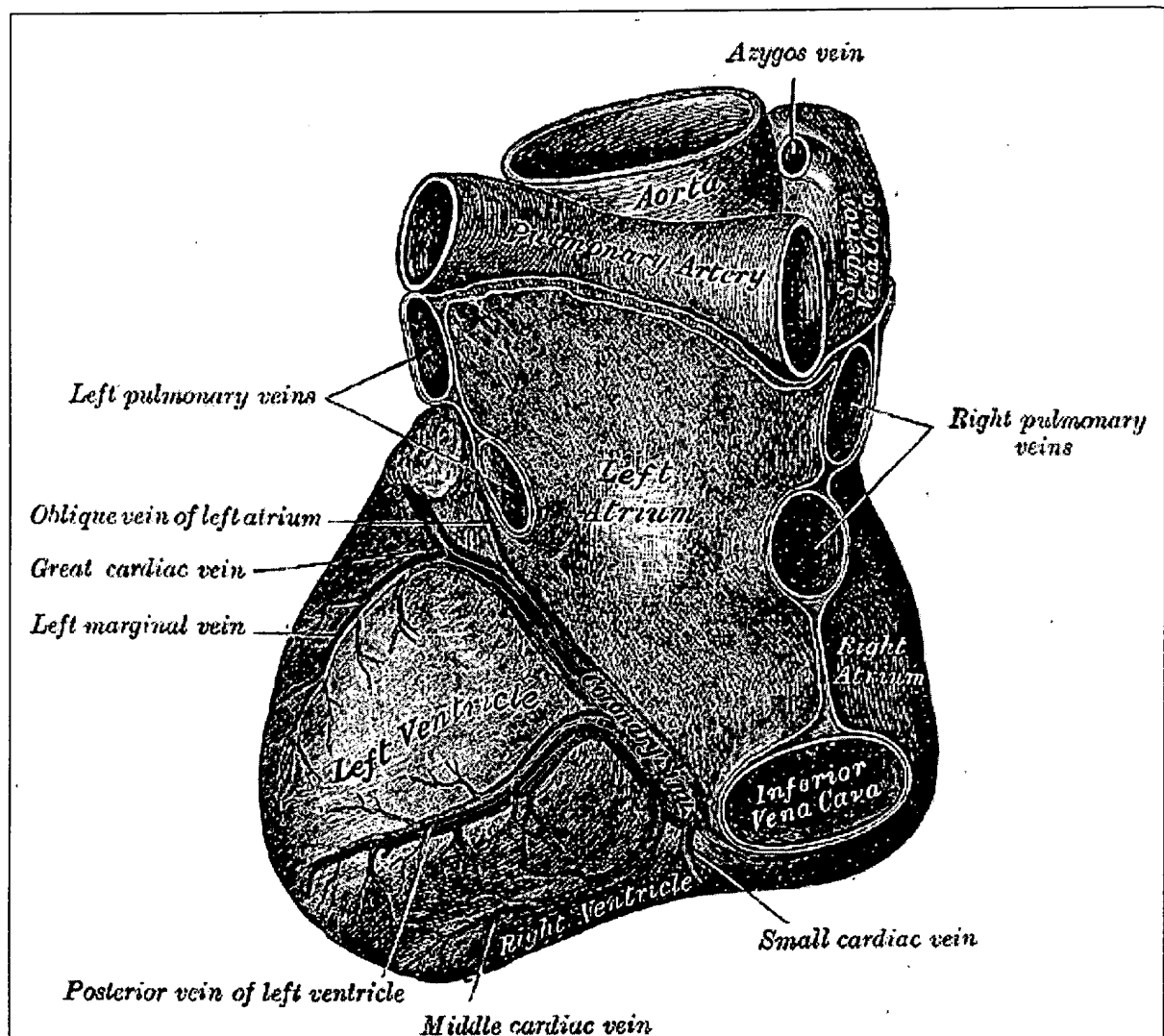


FIG. 556 - Base and Diaphragmatic Surface of Heart.

According to Gray's Anatomy of the Human Body, "most of the veins of the heart open into the coronary sinus." (www.bartleby.com/107/166.html, ¶ 2). The tributaries, which are also commonly referred to as branches, of the coronary sinus are "the great, small, and middle cardiac veins, the posterior vein of the left ventricle, and the oblique vein of the left atrium, all of which, except the last, are provided with valves at their orifices." (*Id.*, ¶ 3).

To further explain the difference between a coronary vein and the coronary sinus, Applicants have provided *Merriam-Webster's* definition of a “coronary vein.” According to *Merriam-Webster*, a coronary vein is “any of several veins that drain the tissues of the heart and empty into the coronary sinus.” (Merriam-Webster Online Dictionary, 2005 Ed., available at <http://www.merriam-webster.com/cgi-bin/dictionary?book=Dictionary&va=coronary+vein>). Accordingly, a coronary vein is not the same as the coronary sinus, but rather one of numerous branches opening into the coronary sinus.

Claims 12-15 and 17-18 are dependent on claim 11 and are patentable over Salo for the reasons argued above, in addition to the elements in such claims. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claims 11-12 and 17-18 and the objection of claims 13-15.

Claim 17:

In addition to the foregoing differences, Applicants cannot find in Salo “pacing the heart with the lead, and adjusting delivery of pacing signals in light of the temperature change in the coronary sinus,” as recited in Applicants’ amended claim 17. As pointed out in the Office Action dated February 16, 2005, Salo recites adaptively adjusting electrical impulses delivered to the electrode 16 “based on temperature outputs from the thermal sensor 9.” Thermal sensor 9 is not located within the coronary sinus 6, and therefore does not measure the temperature within the coronary sinus. Rather, thermal sensor 9 measures the temperature within coronary vein 7. (See, e.g., Salo, [0011], describing “[a] lead system includ[ing] . . . at least one thermal sensor at a distal end of the lead system”; Salo, [0039], stating that “[the] distal end of the lead system 1 is lodged into the coronary vein 7”; Salo, FIG. 2; Salo, [0040], stating that “lead system 1 includes at least one thermal sensor 9 at a distal tip”).

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claim 17.

Claims 18:

In addition to the foregoing differences, Applicants cannot find in Salo “using the temperature change in the coronary sinus as an indicator of a change in the functional status of the heart,” as recited in Applicants’ amended claim 18. The Office Action dated February 16, 2005 implicitly acknowledges that Salo does not describe using temperature changes in the coronary sinus as an indicator of a change in the functional status of the heart; however, the Office Action asserts that “a change in activity would inherently change the functional status of the heart.” (Office Action, pp. 4). Applicants respectfully traverse this Office Action assertion on at least the following ground.

As discussed above, for inherency to be established, “extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *In re Robertson*, 169 F.3d at 745. Applicants assert that the extrinsic evidence does not make clear that “temperature changes in the coronary sinus [for use] as an indicator of a change in the functional status of the heart” is necessarily present in Salo.

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claim 18.

Claims 26 and 29-32:

Applicants have amended claim 26 to include the subject matter of claim 30. As a result, Applicants’ claim 26 contains similar limitations as Applicants’ amended claim 11 and Applicants’ amended claim 17, including “pacing the heart with the lead, and adjusting delivery of pacing signals” using a temperature measured “in the coronary sinus,” and is patentable over Salo for similar reasons. (*See* Applicants’ claim 26).

Claims 27-29 and 31-32 are dependent on claim 26 and are patentable for the reasons argued above, in addition to the elements in such claims. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claims 26, 29, 31-32 and the objection of claims 27-28.

Claim 31:

Applicants' claim 31 contains similar limitations as Applicants' claim 18, including the use of "temperature changes in the coronary sinus as an indicator of a change in the functional status of the heart," and is patentable over Salo for similar reasons.

Claim 32:

In addition to the foregoing differences, Applicants cannot find in Salo "providing pacing pulses to the electrode when a decrease in temperature in a first thermal sensor is detected," as recited in Applicants' claim 32. The Office Action dated February 16, 2005 implicitly acknowledges this fact; however, the Office Action asserts that because "Salo detects a difference in the sensed temperature, [it] therefore inherently detects a decrease in temperature." (Office Action, pp. 4). Applicants respectfully traverse this Office Action assertion on at least two grounds.

First, Applicants assert that the extrinsic evidence does not make clear that "providing pacing pulses to the electrode when a decrease in temperature in a first thermal sensor is detected" is necessarily present in Salo, as required by case law.

Second, Applicants cannot find on page 1, paragraph 9 of Salo, as asserted by the Office Action dated February 16, 2005, any discussion of the detection of a difference in temperature using a single thermal sensor, as required by Applicants' claim 32. Rather, Salo describes "sen[sing] a temperature difference between [a] ventricular thermal sensor and [a] thermal sensor(s) at a distal end of [a] sensing catheter. [. . .] The detector/energy delivery system [] modify[ing] the delivery of electrical signals based on the sensed temperature difference." (Salo, pp. 1, para. 9).

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claim 32.

Allowable Subject Matter

Applicants acknowledge the allowance of claims 19-25. Applicants further acknowledge the allowability of claims 13-15 and 27-28 if rewritten to incorporate the elements of their parent claims, and reserve the right to rewrite such claims pending the outcome of the next Office communication. (Office Action dated February 16, 2005, pp. 6).

Reservation of Right to Swear Behind References

Applicants reserve the right to swear behind any reference(s) which is/are cited in a rejection under 35 U.S.C. §§ 102(a), 102(e), 103/102(a), or 103/102(e). Statements distinguishing the claimed subject matter over the cited reference(s) are not to be interpreted as admissions that the reference(s) is/are prior art.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

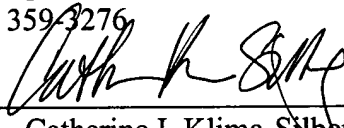
Respectfully submitted,

QINGSHENG ZHU ET AL.

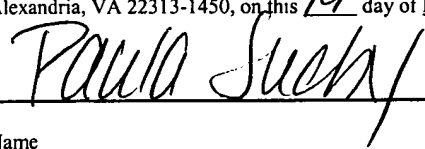
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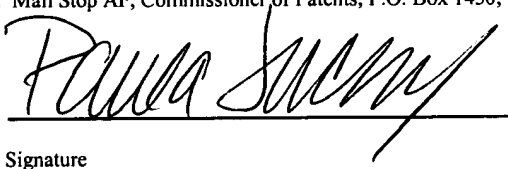
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Date May 19, 2005

By 
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